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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/605,054	06/28/00	CHARIOT	M P62285US1

EXAMINER	
BERMAN,A	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/605,054	Applicant(s) CHARIOT ET AL.	
	Examiner Alysia Berman	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

1. Receipt is acknowledged of the request for extension of time, amendment, certified translation of priority document FR 96/02662 and information disclosure statement filed April 9, 2001 and the terminal disclaimer filed May 25, 2001. Claims 1-20 have been canceled. Claims 24-43 have been added. Claims 21-43 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 25 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 25 is indefinite because it recites "between 0.3 and 1. 26." in line 3. It is unclear what Applicant intends to claim as the weight ratio of mizolastine to organic acid.

5. Claim 29 recites the limitation "L-tartaric acid" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 21, 22, 24-26, 30-34, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,590,062 ('062) in combination with the HCAPLUS abstract of Desager et al., *Pharmacokinetic-pharmacodynamic relationships of H1-antihistamines*, Clin. Pharmacokinet. (1995) 28(5):419-32.

US '062 discloses a controlled and continuous release dosage form containing a matrix made from a fatty acid material, a neutral lipid or, preferably, a combination of both (abstract and col. 3, lines 43-45). Coated tablets are taught at column 1, lines 51-53. The matrix is made of an admixture of a fatty acid consisting of 12-28 carbon atoms such as stearic acid and palmitic acid (organic acids) and a neutral lipid such as stearin, palmitin, castorwax (hydrogenated castor oil) and glycerides (col. 3, lines 19-44). See also column 7, line 43 to column 8, line 10 for fatty acids, lecithin and hydrogenated castor oil. US '062 teaches that antihistamines are suitable biologically active materials for use in the dosage forms. (col. 5, line 16).

US '062 teaches that the percentage of components in the formulation can be varied to modify the controlled release rate of the active agent (col. 3, lines 56-60). Varying the percentages of components would inherently vary the weight ratios of components and the specific amounts of components. US '062 does not teach the antihistamine mizolastine. Desager et al. teach that mizolastine is an effective antihistamine that does not cause drowsiness.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the composition of US '062 and substitute mizolastine of Desager

et al. for the antihistamine expecting to obtain a controlled and continued release antihistamine tablet that does not cause drowsiness.

8. Claims 21, 22, 24-26, 30-34, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,656,296 (296) in combination with Desager et al.

US '296 discloses a sustained release drug delivery system comprising a core with a coating (abstract). The core contains about 60-90% of a medicament and an edible material (abstract). US '296 teaches fatty acids (organic acids) containing 4-22 carbon atoms (col. 4, lines 60-66) such as hydrogenated castor oil, stearic acid and mixtures thereof (col. 5, lines 17-30). Antihistamines are discloses at column 3, line 45. For coated tablets, see column 7, lines 22-41. US '296 does not teach mizolastine.

Desager et al. teach that mizolastine is an effective antihistamine that does not cause drowsiness. It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the composition of US '296 and substitute mizolastine of Desager et al. for the antihistamine expected to obtain a sustained release antihistamine delivery system that does not cause drowsiness.

9. The prior art composition contains the same components and would inherently exhibit the same properties, i.e. dissolution profile. Burden is shifted to Applicant to show that the compositions of the prior art do not exhibit the instantly claimed dissolution profile. Additionally, because it is considered within the skill in the art to adjust the percentages, amounts and weight ratios of materials in order to achieve an optimal dissolution profile, this limitation is not given patentable weight absent evidence of unexpected results.

10. Claims 27-29, 35-37 and 39-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,590,062 ('062) in combination with Desager et al. as applied to claims 21, 22, 24-26, 30-34, 38 and 39 above, and further in view of US 5,102,666 (666).

US '062 and Desager et al. teach all the limitations of the claims as stated in the 35 U.S.C. 103(a) rejection above. Neither reference teaches the organic acids of claims 27-29, 35-37 and 39-43, specifically L-tartaric acid. US '666 teaches that tartaric acid can be added to controlled release tablets containing antihistamines for flavoring and breath freshening.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the composition of US '062 and Desager et al. and add tartaric acid as taught by US '666 expecting to obtain a controlled release antihistamine tablet with a pleasant taste and breath freshening properties.

11. Claims 27-29, 35-37 and 39-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,656,296 (296) in combination with Desager et al. as applied to claims 21, 22, 24-26, 30-34, 38 and 39 above, and further in view of US 5,102,666 (666).

US '269 and Desager et al. teach all the limitations of the claims as stated in the 35 U.S.C. 103(a) rejection above. Neither reference teaches the organic acids of claims 27-29, 35-37 and 39-43, specifically L-tartaric acid. US '666 teaches that tartaric acid can be added to controlled release tablets containing antihistamines for flavoring and breath freshening.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the composition of US '296 and Desager et al. and add tartaric acid as taught by US '666 expecting to obtain a controlled release antihistamine tablet with a pleasant taste and breath freshening properties.

12. US '666 encompasses both a racemic mixture and any individual isomers of tartaric acid. Nothing unobvious is seen in substituting one isomer for another or for the racemic mixture. One of ordinary skill in the art would expect that structurally similar isomers would exhibit similar properties. Therefore, absent evidence of unexpected results, the limitation of the L-isomer of tartaric acid does not render the claims patentable over the prior art.

Response to Arguments

13. Applicant's arguments with respect to claims 1-23 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703-308-4638. The examiner can normally be reached on Monday through Friday from 8:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone numbers

for the organization where this application or proceeding is assigned are 703-305-3592 or 703-305-4556 for regular communications and 703-308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234 or 703-308-1235.

DIANA DUDASH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Alysia Berman
Patent Examiner
June 5, 2001